

AMENDED IN SENATE APRIL 20, 2006

AMENDED IN SENATE MARCH 30, 2006

SENATE BILL

No. 1763

Introduced by Senators Figueroa and Kuehl

February 24, 2006

An act to add Division 112.7 (commencing with Section 130675) to the Health and Safety Code, relating to compulsory licensing of pharmaceutical drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 1763, as amended, Figueroa. Pharmaceuticals: compulsory licensing.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would authorize the Governor to issue a declaration of ~~necessity~~ *a state of emergency to allow* for compulsory licensing of pharmaceuticals if specified conditions are met. The bill would also authorize the department to issue a license for the manufacture of the pharmaceutical drug described in the declaration of ~~necessity~~ *a state of emergency*, and include other related provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 ~~SECTION 1. The Legislature finds and declares all of the~~
2 ~~following:~~

3 ~~(a) The World Health Organization has recommended that~~
4 ~~governments stockpile antiviral drugs to limit the spread of a~~
5 ~~potential influenza pandemic.~~

6 ~~(b) The Infectious Disease Society of America has advocated~~
7 ~~that the federal government stockpile sufficient medicines to treat~~
8 ~~25 to 40 percent of the population of the United States.~~

9 ~~(c) The United States has fallen far short of achieving the~~
10 ~~President's goal of stockpiling enough antiviral medications to~~
11 ~~treat 81 million individuals in the event of a flu pandemic, with~~
12 ~~the current stockpile at approximately 4.3 million courses.~~

13 ~~(d) There is question as to the ability of existing~~
14 ~~pharmaceutical manufacturers to produce sufficient supplies of~~
15 ~~antiviral medications in a near-term timeframe to meet the~~
16 ~~treatment goals recommended.~~

17 ~~(e) Voluntary or compulsory licensing to manufacturers other~~
18 ~~than existing rights holders can be used to produce generic~~
19 ~~versions of needed medications in a health emergency, such as~~
20 ~~the antiviral medications needed to limit the spread of a potential~~
21 ~~influenza pandemic.~~

22 ~~(f) Compulsory licensing is used in other industries in the~~
23 ~~United States.~~

24 ~~(g) There is federal statutory authority to authorize the federal~~
25 ~~government to use compulsory licensing in the pharmaceutical~~
26 ~~industry.~~

27 ~~(h) The World Trade Organization allows countries to issue~~
28 ~~compulsory licenses for pharmaceuticals to address public health~~
29 ~~needs.~~

30 ~~(i) Compulsory licensing could be used by the state to ensure~~
31 ~~sufficient production of needed medications in a health~~
32 ~~emergency, with reasonable compensation to the rights holder, if~~
33 ~~voluntary licenses are insufficient to meet public health needs.~~

34 ~~SEC. 2.~~

35 ~~SECTION 1. Division 112.7 (commencing with Section~~
36 ~~130675) is added to the Health and Safety Code, to read:~~

DIVISION 112.7. COMPULSORY LICENSING OF
PHARMACEUTICAL DRUGS

130675. For purposes of this division, the following definitions shall apply:

(a) “Department” means the State Department of Health Services.

(b) “Use by the state” means the provision of a pharmaceutical drug subject to the license allowed pursuant to this division to an individual for whom the state provides financial payment or assistance for health benefits, including state employees, beneficiaries of Medical, beneficiaries of Medi-Cal, and other state pharmacy programs, individuals under the supervision of the Department of Corrections and Rehabilitation, free health clinics, and beneficiaries of workers’ compensation.

130676. (a) The Governor may ~~issue a declaration of necessity~~ *declare a state of emergency to allow* for compulsory licensing pursuant to this division to address a public health ~~emergency need~~.

(b) The declaration of ~~necessity~~ *a state of emergency to allow* for compulsory licensing shall include all of the following:

~~(1) The public health and safety basis for issuing the license to manufacture, which may consider whether adequate access to a pharmaceutical is essential for maintaining health or life.~~

~~(1) The public health and safety emergency for which issuing the license to manufacture is necessary.~~

(2) A list of the relevant patents, exclusive marketing periods, copyrights, trademarks, and any other relevant property to be licensed under this division.

(3) The proposed license, including ~~royalty rate~~ *proposed compensation rate*.

(c) The department shall establish a process to notify the public of the declaration of necessity and to disseminate information to pharmacists, local public health officers, and any other individuals or groups, as deemed necessary by the department.

(d) The notice of the declaration of ~~necessity~~ *a state of emergency to allow for compulsory licensing* and a copy thereof shall be sent to the registered agent in the state of incorporation of each company that may be affected by the ~~licensing within~~

1 ~~five days of the declaration of necessity being published in one~~
2 ~~newspaper.~~ *licensing.*

3 (e) The licensure process shall be conducted by the department
4 *and shall ensure due process to any company affected by the*
5 *license.*

6 130676. (a) The department shall establish a process to
7 permit any person affected by the compulsory licensing may
8 appeal the licensure of the property listed in the declaration.

9 (b) If no notice of intervention is filed, the department may
10 issue the license pursuant to Section 130677.

11 130677. (a) If the requirements of Sections 130675 and
12 130676 are met, the department may issue a license for the
13 manufacture of the pharmaceutical drug described in the
14 declaration of ~~necessity~~ *a state of emergency to allow for*
15 *compulsory licensing.* In addition the department shall notify the
16 owner of the property being licensed of the amount of just
17 compensation and any terms or conditions contained in the
18 opinion of the department after the expiration of the appeal
19 period.

20 (b) The department may assign the license to one or more
21 manufacturers of pharmaceutical drugs solely for the
22 manufacture of the pharmaceutical drug for the use by the state
23 and other states that have issued substantially similar licenses.

24 130678. Nothing in this division shall operate as a waiver of
25 the state's sovereign immunity.